

## II. 35 U.S.C. § 112, First Paragraph

Claims 25-27 were rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Office action at 2. The PTO reasoned that “there is no support in the specification for the recitation ‘amount ranging from 0.1 mg to 10,000 mg.’” Office action at 2. The PTO noted that, instead, the specification at page 14, lines 24-25, states that “dosage levels are from ‘*about* 0.1 mg to about 10,000 mg’ of the active ingredient compound.” Office action at 2-3 (emphasis added). The PTO noted that “nowhere in the specification is the amount recited without the word ‘about.’” Office action at 2. Applicants respectfully traverse this rejection.

The evidence and explanation of record are insufficient to establish a prima facie case of failure to meet the written description requirement. MPEP § 2163.04. The PTO “must have a reasonable basis to challenge the adequacy of the written description.” MPEP § 2163.04. Initially, the PTO has the burden of presenting evidence and explanation establishing “why a person skilled in the art would not recognize in an applicant’s disclosure a description of the invention defined by the claims.” MPEP § 2163.04. But the burden was not met here.

In this case, the PTO based its prima facie case solely on the presence of the word “about” in the specification as filed and the absence of the word “about” in the rejected claims. Office action at 3. The PTO failed, nevertheless, to explain why those skilled in the art would not consider the term ‘*about* 0.1 mg to about 10,000 mg’ in the specification as-filed to support 0.1 mg to about 10,000 mg. Indeed, the PTO never stated which ranges those skilled in the art would have considered supported by the specification as-filed. Here, the later range is clearly derivable from the specification as-filed. *Cf. Ralston Purina Co. v. Far-Mar-Co., Inc.*, 772 F.2d 1570, 1575, 227 U.S.P.Q. 177, 179 (Fed. Cir. 1985). Thus, the PTO failed to establish a prima facie rejection.

Moreover, the PTO’s conclusion, that “there is no support in the specification for the recitation ‘amount ranging from 0.1 mg to 10,000 mg,’” does not reasonably follow from the

evidence and explanation of record. The PTO admitted the application teaches “dosage levels are from ‘*about* 0.1 mg to about 10,000 mg’ of the active ingredient compound.” Office action at 2-3 (emphasis added). Notwithstanding the presence of the term “about,” the cited term contains two reference points, *i.e.*, 0.1 mg and 10,000 mg. Why, then, would one skilled in the art fail to recognize support for “0.1 mg to 10,000 mg”? The rejection provides no answer.

Accordingly, the rejection is improper and must be withdrawn.

### **III. Double Patenting Rejection**

Claims 25-27 were rejected under the judicially-created doctrine of obviousness-type double patenting as unpatentable over claims 22-24 of U.S. Patent No. 6,239,164. Office action at 3. However, the '164 patent cannot be used as a reference in this case. *See* 35 U.S.C. § 121. Thus, the rejection is improper and must be withdrawn.

### **IV. Conclusion**

Applicants believe that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned attorney by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

Respectfully submitted,

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The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extension under 37 CFR § 1.136 and authorize payment of any such extensions fees to Deposit Account No. 19-0741.